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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,015	02/17/2005	Noboru Yamaji	Q86324	5025

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WASHINGTON, DC 20037-3213

EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,015	YAMAJI ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment / Arguments

Applicant's amendments and arguments filed September 4, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Applicant has introduced new claim 18, necessitating new grounds of rejection below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 13-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by KAMMER (PTO-1449, 6/24/05) for the reasons of record and those set forth below.

Applicant's arguments are iterative of previous arguments, in that Applicant argues that Kammer, "implies that the autoimmune diseases include a broad range of disease from systemic diseases to local ones. In actuality, however, Kammer merely shows an improvement in proteinuria...and there is no disclosure of a specific effect on rheumatic arthritis (joint) therein." (page 5, remarks 11/27/06). Applicant further asserts that the target of Kammer is not the same as the instant invention, presenting secondary references in support of the position that the cause of RA is not well understood or well known.

Respectfully, the examiner disagrees. As discussed previously, Kammer specifically *claims* treating rheumatoid arthritis (herein 'RA') with the HDACi (referenced below). Since ACEM is an underlying condition/feature of RA, in treating RA, one is necessarily inhibiting ACEM degradation and the associated inflammation (arthrosteitis). Applicant does not argue or

dispute that Kammer teaches- and claims- treating RA with HDACi (below), but rather argues that it was not understood what was believed to be the underlying mechanism, however as discussed previously, in treating RA with the HDACi, one is inherently practicing the instantly claimed invention. Applicant is reminded that the inherent feature and necessary result, here being the inhibition of ACEM degradation, need not be recognized at the time of the invention and occurs when practicing the method of Kammer (cf. MPEP § 2112 (II), citing *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004), "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").

The instant claims are drawn generally to administering HDACi in inhibiting ACEM and treating arthrosteitis, rheumatoid arthritis (herein 'RA') or osteoarthritis caused by ACEM.

The teachings of Kammer have been presented previously (*see* Office Action 4/20/06, pages 11-12). Kammer teaches a method of treating RA with a histone hyperacetylating agent (claim 10). In looking to the specification for the preferred embodiments of the histone hyperacetylating agent usable in the method, the specification provides that HDACi are the preferred compounds (citing WO 97/11366), providing exemplary HDACi usable in the methods, including trichostatin A, SBHA, SAHA, apicidin (e.g *Specification pages 6-8*) and specifically embodies in the claims (e.g. claims 3-9) trichostatin A, trapoxin A, FK228 (FR901228) and MS-275 (MS-27-275). Kammer teaches that the compounds are preferably administered at 1 μmol/kg to 50 μmol/kg, more preferably at 22 μmol/kg to 33 μmol/kg for oral and i.v. administration, thus being of an overlapping, if not commensurate scope of the instantly

disclosed preferred dosages. Further, in treating RA one would be treating/inhibiting the underlying conditions, e.g. ACEM. Additionally, it is noted that Applicant admits in the instant specification that Kammer teaches treating RA with HDACi (spanning pages 6-7 of the instant specification).

Claims 11 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WATKINS (WO 02/30879 A2). Watkins has been introduced in response to new claim 18, and it has been determined that Watkins may be appropriately applied to claims 11 and 13-17.

The instant claims are presented *supra*. Watkins teaches that HDACi are well known for treating osteoarthritis and RA (e.g. page 111, lines 1 and 2) and teaches a myriad of HDACi, including those instantly claimed (e.g. trichostatin A and SAHA, page 4). Thus, in treating osteoarthritis or RA and the associated inflammation with the HDACi, one is inherently inhibiting/treating the underlying conditions, e.g. ACEM degradation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew D Kosar
Patent Examiner
Art Unit 1654